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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/482,599	01/13/2000	Randy Kristopher Bower	CDS-0215	7220

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EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 05/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

MEL

Office Action Summary	Application No.	Applicant(s)
	09/482,599	BOWER ET AL.
	Examiner	Art Unit
	P. Kathryn Bex	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 March 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
 - 4a) Of the above claim(s) 5-17 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 January 2000 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-4, in Paper No. 5 is acknowledged. Because applicant did not *distinctly* and *specifically* point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: #175 in Figure 2B, see page 10, line 22. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Examiner notes the copy of the Figure 2B submitted with the Amendment filed March 11, 2002, however this is not a copy of original Figure 2B, see attached Figure 2B. Correction is required.

Claim Rejections - 35 USC § 112

3. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Instant claim 1 now recites, "a method for detecting failures that can result from multiple failure modes in an analyzer...". However, the specification does not support "a method for detecting failures that can result from *multiple failure modes*, but rather multiple detection schemes (i.e. error detection measures), are used for the detection of the **same** failure mode, see page 7, lines 22-29. Furthermore, the specification states "[b]y taking advantage of

the multiplying effect of multiple detection schemes targeting the **same** failure mode, each detection scheme does not have to be extremely robust in order to achieve a robust detection system."

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 now recites within the preamble, "a method for detecting failures that can result from multiple failure modes", the conditional term "can" is not a positive recitation, therefore, renders the claim indefinite.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A process that consists solely of the manipulation of an abstract idea is not concrete or tangible. Claim 1, recite steps: a) "identifying potential errors", b) "identifying potential sources of the potential errors", d) "identifying potential error detection measures", such limitations are considered abstract ideas, or mental steps. The specification does not provide support as to *how* the potential errors and potential sources are *identified*. See *In re*

Warmerdam, 33 F.3d 1354, 1360, 31 USPQ2d 1754, 1759 (Fed.Cir. 1994). See also *Schrader*, 22 F.3d at 295, 30 USPQ2d at 1459.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by *Hoth et al* (USP 5,710,723).

Hoth et al teach an automated method and apparatus for performing pre-emptive maintenance on operative devices involved in the processing, transport and distribution of chemicals. The method of performing pre-emptive maintenance requires that the sources of potential errors that can result in failures be identified, e.g. pumps, motors, pipes, transformers, etc. Moreover, multiple sensors (e.g. error detection measures) corresponding to the sources of potential errors, e.g. pumps, motors, are used (column 4, lines 26-31). In a learn mode, the system collects data from operating equipment at periodic intervals via the sensors, i.e., multiple sensors provides data for the corresponding source of errors such that the probability of a false positive is reduced. A failure probability calculation for each error detection measures is performed in monitor mode, which compares the learned mode norms with monitor mode data obtained and a potential for failure, i.e. false positive, is estimated (column 9, line 44- column 10, line 64). Next, data from a reference library is used to apply the appropriate maintenance action in order to keep the process operating without interruption. The system includes the use

of a control processor employing linear programming processes (column 3, lines 47- column 4, line 35). Note: language that suggests or makes optional but does not require steps to be performed does not limit the scope of a claim or claim limitation. Statements of intended use or field of use, i.e. for conducting clinical assays, do not provide a limiting effect of the language in the claim.

10. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Farmer (USP 5,315,529).

Farmer teaches an automated fluid vessel leak existence system method and apparatus. The method identifies the probability of a potential leak in a fluid storage tank or other containment device, including piping. Error detection measures, sensors, corresponding to the source of the potential leak are utilized within the system. A signal conditioner receives raw data from the sensors, this data is converted into a signal, which is sent to a statistical filter. The filter analyzer can determine the probability that a leak has occurred. Additionally, qualifying logic may be programmed to improve the accuracy of the leak detector by causing a monitor to ignore signals representing leak detection when certain conditions exist making a false leak detection likely, (columns 3-8). Note: language that suggests or makes optional but does not require steps to be performed does not limit the scope of a claim or claim limitation. Statements of intended use or field of use, i.e. for conducting clinical assays, do not provide a limiting effect of the language in the claim.

Response to Arguments

11. Applicant's arguments filed March 11, 2002 have been fully considered but they are not persuasive. In response to the rejection of claims 1-4 under 35 U.S.C. 102(b) as being

anticipated by Hoth *et al* (USP 5,710,723), Applicant argues that Hoth *et al* is directed to the operation of industrial equipment, not analytical/clinical instrumentation. However, no step for *recited* conducting clinical assays are *disclosed* within the instant claims, therefore the recitation of "an analyzer for conducting clinical assays" is considered an intended use. Statements of intended use or field of use do not provide a limiting effect of the language in the claim, see *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Additionally, the recitation "analyzer for conducting clinical assays" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the **process steps** or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Applicant argues that Hoth *et al* makes no mention of selection of detection measures that are based on the multiple measures that are based on the heightened probability of error detection one attains from the multiplicative probabilistic effect of multiple measures for detecting each failure mode while reducing the probability of a false positive error detection. Examiner does not agree. Hoth *et al* teaches operative devices (i.e. pumps, motors, etc) involved in the processing, transport and distribution of chemicals are provided with error detection sensors (column 4, lines 26-31). Moreover, the probability that an error source, i.e. pump, motor, etc, will fail is determined by various modes. The system collects data from this operating equipment at periodic intervals via the sensors. A failure probability calculation is performed in monitor

mode, which compares the learned mode norms with monitor mode data obtained and a potential for failure of the sensors is estimated. Next, data from a reference library is used to apply the appropriate maintenance action in order to keep the process operating without interruption (column 3, lines 47- column 4, line 35).

In response to the rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Farmer (USP 5,315,529), Applicant argues that Farmer is directed to detecting one type of event, i.e. a leak. Additionally, Farmer is not directed to assay failure at all, *let alone* assays for which failures can be detected. Examiner does not agree since one example disclosed within the specification describes a failure which could occur if an ineffectual quantity of reagent is used, i.e. one type of failure. Moreover, one cause of such a failure is a leak, see paragraph bridging pages 15-16 in the instant specification. Additionally, the instant claims have not restricted the scope of the claim such that a *single* failure mode, i.e. leak, cannot be detected by a plurality of sensors, i.e. multiple error detection measures, since the recitation of multiple failure modes occurs within the preamble.

Conclusion

12. No claims allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

Art Unit: 1743

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex

P. Kathryn Bex

Patent Examiner

AU 1743

May 28, 2002

Jill Warden

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